DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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January 10, 2003

WARNING LETTER

NWE-08-03W

VIA FEDERAL EXPRESS

Joseph P. Krieger, President
Krieger Medical, Inc.
3A Gill Street
Woburn, Massachusetts 01801

Dear Mr. Krieger:

An inspection of your facility located in Woburn, Massachusetts, was conducted on October 1 and 4, 2002, by Investigators George T. Allen and Alan R. Condon. Our investigators found that your facility manufactures fluoroscopic imaging tables. This product is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigators documented several significant deviations from the Quality System Regulation (QS Regulation) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the device you manufacture to be adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the QS Regulation as follows:

1. Your firm failed to conduct quality audits at the intervals listed in your Quality Audit Procedure 0200, to verify that the quality system is effective, as required by 21 CFR 820.22. For example, no quality audits have been performed by your firm.

2. Failure to document acceptance activities as required by 21 CFR 820.80(e). For example, approximately two hundred and fifty (250) device history records (DHRs) were reviewed during the inspection. None of the DHRs included any results for finished product acceptance activities.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS Regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

This is also to acknowledge receipt of your letter dated October 17, 2002, that responds to the FDA-483 that was issued to you at the close of inspection on October 4, 2002. Your response is not adequate for the following reasons. 1.) During the inspection, the investigator reviewed over 250 DHRs and none were complete. Further, your response did not include any documentation to support your claim. 2.) No Quality Audits have been performed by your firm following the QAP/0200 procedure.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted QS Regulation violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Bruce R. Ota, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Gail T. Costello
District Director
New England District